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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/387,135      08/31/99      COSFORD

N      SIBIA1290

EXAMINER

HM12/0313

MERCK & CO., INC.  
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CHOI, F  
ART UNIT      PAPER NUMBER

1616  
DATE MAILED:

03/13/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/387,135

Applicant(s)

COSFORD ET AL.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of 2-methyl-4-(phenylethynyl)-1,3-thiazole in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the proposed expanded group would not constitute an undue burden. In light of the fact that the elected compound appears to be novel, Examiner has expanded the search to the extent of the amended claims.

### ***Claim Objections***

Claims 1-10 are objected to because of the following informalities: Dependent claims should begin with a "The". Claim 1, 5<sup>th</sup> line after the structure there is a period mark after "unsubstituted". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the examples which exhibit activity on the hmGluR5a receptor and/or analgesic activity at the specified doses in rats, does not reasonably provide enablement for the other compounds, the modulation of all amino acid receptors, the treatment of the disease conditions or prevention of the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant claims a numerous possible combinations of compounds and methods of using the same, however, the disclosure appears to

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provide relatively few examples and those examples exhibit varying degrees of effectiveness with only four compounds being tested for analgesic effectiveness. It is notoriously well known that the effectiveness of the drug depends on the subject being treated, formulation of the dosage form, the particular disease state or condition, the therapeutic threshold and mode of administration. However, the disclosure appears to provide little direction as to any of these factors. Further, it is notoriously well known that no single compound is effective in treating every disease condition or even every disease condition specified in the claims. Examiner notes that in a number of disease states falling within the scope of Applicant's claims the state of the art treatment is limited to alleviation of symptoms or slowing down the progression of the disease without treating or curing the underlying disease; for example, Alzheimer's and Parkinson's disease. The disclosure other than testing four of the compounds for analgesic effect does not appear to show that any of the compounds would be effective in treating the disease states listed. As such, it is highly improbable that the compounds herein would be effective against every disease state listed. Finally, the term "prevent" implies that the compound will completely prevent even a single cell being effected by the disease state and that the subject treated will never again be effected by the disease. While a given compound may inhibit, or reduce the risk of a given disease state it is highly improbable that the claimed compounds would be effective in preventing the disease states listed nor does the disclosure appear to provide evidence of the same. In light of the above, a skilled artisan would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims.

***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9-11 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 96/33181.

WO 96/33181 expressly discloses an ethynylthiazole derivative, and salt thereof, and a method of using the same falling within the scope of applicant's claims (Pgs. 63-66, Text Examples 1,2, Claims 1-22).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Claims 4, 5, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/33181.

WO 96/33181 teach a an ethynylthiazole derivative, and salt thereof, and a method of treating and preventing various diseases, including cerebral ischemia, angina pectoris (Pgs. 37-40, 62-68, Claims 1-22).

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The difference between the cited reference and the claimed invention is that the claimed reference does not expressly disclose a toluene sulfonic salt of the claimed compounds.

However, the cited reference amply suggests the same as pharmaceutically acceptable salts are well known in the art. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use any of a number of salts, including toluene sulfonic salt, with the expectation that they would be pharmaceutically acceptable (See Pg. 38).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

#### ***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

March 9, 2001



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1200

